ARC 3764C

PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to interchangeable biological products and labeling requirements and providing an opportunity for public comment

The Pharmacy Board hereby proposes to amend Chapter 18, "Centralized Prescription Filling and Processing," and Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2017 Iowa Acts, House File 305.

Purpose and Summary

The proposed amendments incorporate language from 2017 Iowa Acts, House File 305, signed into law during the 2017 Legislative Session of the 87th General Assembly, which allows the substitution of interchangeable biological products and includes labeling requirements.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on May 15, 2018. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309-4688
Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental

subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend subrule 18.3(4) as follows:

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. to *c.* No change.

d. ~~The~~ Except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors or 657—subrule 8.19(8) for opioid antagonists, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. to *g.* No change.

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)"~~.~~;

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)";

i. The initials or other unique identification of the pharmacist ~~in the originating pharmacy~~ who performed drug use review ~~and transmitted the prescription drug order to the central fill pharmacy~~.

ITEM 2. Amend subrule 22.1(3) as follows:

22.1(3) *Labeling requirements.*

a. and *b.* No change.

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)".

d. and *e.* No change.

ITEM 3. Amend subrule 22.5(5) as follows:

22.5(5) *Labeling requirements.*

a. to *c.* No change.

d. If a pharmacist selects a generically equivalent drug product for a ~~brand-name~~ brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the

~~brand-name~~ brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (~~brand-name~~ brand name product)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)".